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5 Title of the Invention: Sterilization Process

Application No. Hei 2-19156

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Specification

15 1. Title of the Invention: Sterilization Process

2. Claims.

(1) A sterilization process comprising sealing a material to be sterilized and a liquid into a closed container, rapidly increasing 20 a pressure in the closed container up to 1,000 to 3,000 kg/cm², and repeating the following steps: maintaining this pressure for a predetermined duration, and then rapidly reducing and increasing the pressure in the closed container.

(2) The sterilization process according to claim 1, wherein ultrasonic 25 vibration is applied to the liquid in the closed container and the material to be sterilized while maintaining the pressure in the closed container at 1,000 to 3,000 kg/cm².

3. Detailed Description of the Invention

30 (Industrial Field of the Invention)

A sterilization process according to the present invention is applicable to sterilization of surgical tools and such, such as scalpels and forceps.

(Prior Art and Problems)

35 Surgical tools, artificial hearts, surgical fats and oils, and the like, to which bacteria are likely to attach or to which bacteria

undesirably attach, must be sterilized before use.

A heating sterilization process using hot and pressurized vapors or a sterilization process using a sterilization gas such as an ethylene oxide gas is conventionally used for this purpose.

5 However, the heating sterilization process cannot be used for materials to be sterilized which cannot resist heat, and the sterilization process using the sterilization gas cannot be used for artificial hearts and the like, which do not accept even the presence of a small amount of residual gas.

10 As another known sterilization process, a pressurization process comprises sealing a material to be sterilized and a liquid such as water into a closed container and increasing the pressure in the closed container up to several thousand kg/cm² to eliminate bacteria from the material to be sterilized.

15 The pressurizing sterilization process, however, increases the pressure in the closed container up to the predetermined value, which is then maintained for a predetermined duration, thus requiring a high pressure and a long time.

The sterilization process of the present invention eliminates 20 all these inconveniences.

(Means for Solving the Problems)

25 The sterilization process of the present invention comprises the steps of sealing a material to be sterilized and a liquid into a closed container, rapidly increasing a pressure in the closed container up to 1,000 to 3,000 kg/cm², and repeating the following steps: maintaining this pressure for a predetermined duration, and then rapidly reducing and increasing the pressure in the closed container.

(Action)

30 In the sterilization process of the present invention described above, as the material to be sterilized which is sealed into the closed container together with the liquid undergoes repeated impact, the cells of bacteria attaching to the material to be sterilized are efficiently destroyed, thereby achieving good sterilization with a 35 relatively low pressure in a relatively short time.

(Examples)

Next, to ascertain the effects of the present invention, experiments conducted by the inventors will be described.

The experiments were conducted using such an apparatus as shown in Fig. 2.

5 A cap 2 is screwed into a main body 1 so that a closed space 3 can be formed between these members 1 and 2. A piston 5 is fitted in a cylinder portion 4 formed inside the main body 1, and a rod 6, having one end coupled to the piston 5, has an opposite end facing the closed space 3. The both ends of the cylinder portion 4 are in
10 communication with an oil pressure source 7 so as to arbitrarily increase and reduce the pressure in the closed space 3 depending on the side of the cylinder portion 4 to which pressure oil is directed. Further, an ultrasonic vibrator 8 is fixed to a top surface of the cap 2 so as to apply ultrasonic vibration to water 9 and a material to be
15 sterilized 10 which are sealed in the closed space 3.

The experimental apparatus constructed as described above was used to sterilize a material to be sterilized comprising a polyethylene bag having a liquid enclosed therein and containing *Escherichia coli* (*E. coli*) at a concentration of 1.1×10^4 /ml.

20 The material was sterilized at a temperature of $15 \pm 5^\circ\text{C}$, and the pressure was varied between $1,000 \text{ kg/cm}^2$ and $1,500 \text{ kg/cm}^2$ and $1,800 \text{ kg/cm}^2$ in order to ascertain the sterilization effect.

First, to carry out the sterilization process of the present invention, the pressure in the closed space 3 was varied as shown
25 in Fig. 1. That is, 15 seconds after the start of the experiments, the pressure in the closed space 3 was increased to a predetermined value, which was then maintained for one minute. The pressure in the closed space 3 was then rapidly reduced and increased against atmospheric pressure within 5 to 10 seconds. Such a cycle was repeated
30 30 times, and then the number of *E. coli* contained in the material to be sterilized was measured. As a result, this number varied depending on the pressure in the closed space 3 ($1,000$ or $1,500 \text{ kg/cm}^2$), as shown with the broken line a in Fig. 3.

On the other hand, the pressure in the closed space 3 was maintained
35 at a fixed value for 30 minutes as shown in Fig. 4, and then the number of *E. coli* contained in the material to be sterilized was measured.

As a result, the number varied depending on the pressure in the closed space 3 (1,000, 1,500, or 1,800 kg/cm²), as shown with the solid line b in Fig. 3.

As is apparent from Fig. 3, with the same pressure and time,
5 the sterilization process of the present invention provides a more excellent sterilization effect than the prior art. Further, it can provide a predetermined sterilization effect with a reduced pressure or time.

(Effects of the Invention)

10 As described above, the sterilization process of the present invention makes it possible to reduce the pressure or time required to obtain a predetermined sterilization effect, thus achieving a relatively inexpensive and efficient sterilization process.

15 4. Brief Description of the Drawings

Fig. 1 is a chart showing how pressure varies when a sterilization process according to the present invention is carried out.

Fig. 2 is a sectional view showing an experimental apparatus.

Fig. 3 is a chart showing results of experiments.

20 Fig. 4 is a chart showing variations in pressure according to a conventional process.

1 Main body

2 Cap

25 3 Closed space

4 Cylinder portion

5 Piston

6 Rod

7 Oil pressure source

30 8 Ultrasonic vibrator

9 Water

10 Material to be sterilized

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Fig. 1

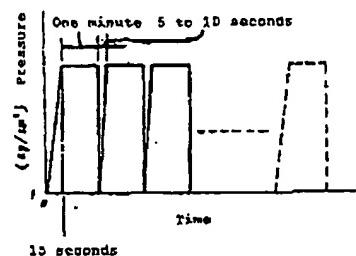


Fig. 2

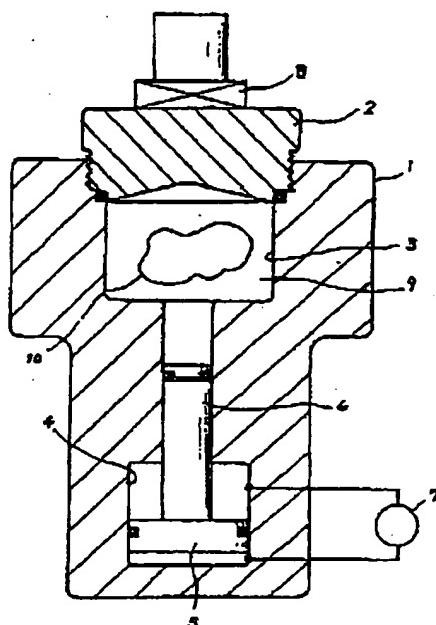


Fig. 3

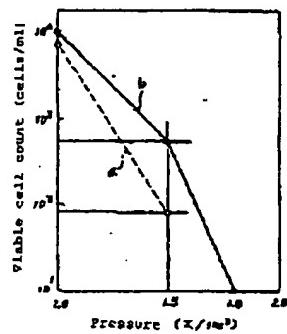


Fig. 4

